

**RULES
OF
TENNESSEE DEPARTMENT OF HEALTH**

**CHAPTER 1200-20-12
ADMINISTRATION OF MEDICATION BY UNLICENSED PERSONNEL
TO PEOPLE WITH MENTAL RETARDATION**

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1200-20-12-.01 DEFINITIONS: As used in these rules, the terms below shall have the following meanings ascribed to them.

- (1) "Administration of medications" shall mean providing for the ingestion, application, injection of medications allowed by these rules, inhalation or rectal or vaginal insertion of medication, including over the counter and prescription drugs, according to the written or printed directions of the attending physician or other authorized practitioner or as written on the prescription label and making a written record thereof with regard to each medication administered, including the time and amount taken, but administration does not include judgment, evaluation or assessment.
- (2) "Adult day programs" shall mean any program licensed or contracted by the Division of Mental Retardation Services to provide day activities to people with mental retardation over eighteen years of age. Such services include day habilitation, follow-along, supported employment and community participation.
- (3) "Competency testing" shall mean a written exam and a practical demonstration of skills that measure basic competency in medication administration.
- (4) "The Board" shall mean the Tennessee Board of Nursing
- (5) "Curriculum" shall mean a detailed course outline, description or syllabus submitted to the Department as part of the approval process of an entity, nursing agency, health care facility or Division sponsoring a medication administration course. At a minimum, a curriculum for approval or re-approval shall contain the following:
 - (a) title
 - (b) names and authors
 - (c) specific course objectives
 - (d) units to be covered in the course
 - (e) hours to be spent in each unit
 - (f) the methods of instruction

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- (g) a description of the practical training to be provided
 - (h) a written test to measure competency in medication administration; and
 - (i) a description of a test to measure competency through a practical demonstration of each required skill
- (6) "Department" shall mean the Tennessee Department of Health.
 - (7) "Division" shall mean the Division of Mental Retardation Services of the Department of Mental Health and Mental Retardation.
 - (8) "Drugs or Medications" shall mean substances intended for use in diagnosis, care, mitigation, treatment, or prevention.
 - (9) "Employee" shall mean an individual who is unlicensed and is employed by a provider agency.
 - (10) "Medication Administration Error" shall mean that a drug was not given in the right amount, in the right strength, at the right time, by the correct route or methods of administration, or to the right individual. Medication administration error shall also mean that a medication was ordered and not administered.
 - (11) "Non-injectable medications" shall mean any medication that is not administered by the intradermal, subcutaneous, intramuscular or intravenous route. This includes medications that are prepackaged and premeasured for oral medication, medications administered through gastrostomy and jejunostomy feeding tubes, prescribed topical, otic, nasal, inhaled medications, ophthalmic medications, and rectal and vaginal suppository medications.
 - (12) "Injectable Medications" shall mean allowed injectable medications which are only to include those medications given routinely by an injectable method to assure the continuation of a state of well-being. These medications are limited to a person requiring insulin injections on a daily basis or one time administration of life saving injections, such as EpiPens for severe allergies.
 - (13) "Licensed Professional Nurse" shall mean a registered professional nurse who is licensed by the State of Tennessee.
 - (14) "Monitoring" shall mean periodic review, observation, direction, and evaluation of an unlicensed individual's knowledge, skills, and performance related to the functions and activities provided for in these rules.
 - (15) "Program coordinator" shall mean the licensed professional nurse in charge of the medication administration training program.
 - (16) "A person receiving services" shall mean any person with mental retardation residing in residential settings or any adult day program funded by the Division of Mental Retardation Services.
 - (17) "Provider Agency" shall mean a private non-profit or for-profit entity licensed by or under contract with the State to provide services to individuals with mental retardation/developmental disabilities through the Division of Mental Retardation Services.
 - (18) "Residential settings" shall mean any program licensed by or contracting with the Division to provide residential services to children or adults with mental retardation. Such services include supported living

(Rule 1200-20-12-.01, continued)

environments, group homes, and family based residential programs as defined in the Division of Mental Retardation's Operations Manual.

- (19) "Supervision" shall mean the initial, as well as subsequent, verification of an unlicensed person's knowledge and skills in the performance of a specific function, as well as during training activities provided for in these rules.
- (20) "Two year medication examination" shall mean the examination administered by the Department or its designee every two years to unlicensed staff approved to administer medications.
- (21) "Unlicensed personnel authorized to administer medications" shall mean a person who
 - (a) is at least eighteen years of age
 - (b) has not been convicted of a crime rationally related to his or her employment,
 - (c) speaks, reads, writes and understands the English Language,
 - (d) has successfully completed an approved medication administration training program,
 - (e) is approved to administer medications by both the Department and the provider agency by which the unlicensed personnel is employed, and
 - (f) maintains such approved status according to the provisions of these rules.
- (22) "Testing entity" shall mean an agency or individual selected by the Department to administer medication administration competency tests, upon completion of a medication administration training program.

Authority: T.C.A. §§4-5-202 and 68-1-904. **Administrative History:** Original rule filed August 21, 1998; effective November 4, 1998.

1200-20-12-.02 TRAINING PROGRAMS

- (1) Approval of Training Programs
 - (a) In cooperation with appropriate agencies or advisory bodies, the Department shall develop or approve initial training curricula and competency evaluation procedures for those unlicensed personnel who administer medications. A qualified testing entity or educational institution may apply to the Department for approval to conduct a Medication Administration Training Program. Upon approval of the curriculum, the Department or its designee may contract with a private provider or instructor to provide such training and administer such competency testing. The Department shall maintain a list of approved medication administration contractors for training.
 - (b) Requests for the approval of a medication administration training program shall be submitted to the Department and include the following:
 - 1. name, address and telephone number of the agency offering the program;

(Rule 1200-20-12-.02, continued)

2. the program coordinator's name, address, RN license number, and verification of a minimum of two years experience, at least one of which must be in the provision of services to people with developmental disabilities and mental retardation;
 3. statement of course objectives;
 4. description of course content specifying the number of hours and key topics to be covered;
 5. a test which measures competency through a practical demonstration of the required skill; and
 6. a written test to reflect and measure the skills and requirements of these rules.
- (c) The Department must respond to a request for approval of a medication administration training program with either a notice of the action taken or a request for additional information within 90 days of the receipt of the application for medication administration course approval.

(2) Course Content

The course curriculum should cover, at a minimum, the following topics:

- (a) introduction to pharmacology;
- (b) legal and ethical aspects of medication administration;
- (c) state and federal regulations regarding medications;
- (d) terminology abbreviations and measurements;
- (e) administration of medications;
- (f) types of medications, their actions, interactions, potential side effects, adverse reactions, and appropriate emergency responses;
- (g) documentation and record keeping; and
- (h) storage and disposal of medication

(3) Instructors

- (a) The instruction of medication administration must be performed by a licensed professional nurse who possesses a minimum of two (2) years of experience, at least one year of which must be in the provision of services to people with mental retardation/developmental disabilities. Training personnel who may supplement the program coordinator including, but not limited to, physicians, licensed practical nurse, pharmacists, and developmental disability administrators which are subject to these rules. Supplemental training personnel must have at least two (2) years of experience in their respective fields.

(4) Review of Courses

(Rule 1200-20-12-.02, continued)

- (a) The Department shall have the authority to review and grant approval of medication administration training programs. It is expected that the training program will keep abreast of current standards and practices in the field.
- (5) Competency Based Medication Administration Training Program Implementation
 - (a) The Department shall assure that training sessions, each to be followed by a competency test set to measure basic competency, are offered at various geographic locations in the state.
 - (b) Approved providers of medication administration training programs must have and maintain procedures for administration, security and validation of tests, and the reporting of scores. results to the Department. Such procedures must include limitations of the number of times a particular test will be used. A pool of questions may be used to develop alternative tests.
 - (c) Each private training contractor shall provide the Department with a list of all persons who have taken an approved training session and has successfully completed a competency test. Such contractor shall also provide the Department with any other pertinent information reasonably requested by the Department.
 - (d) Course attendance records must be maintained for a minimum of two years from the date of completion of the course and are subject to review by the Department upon request.
 - (e) At least 30 days before each occasion on which an approved course is to begin, sponsors of approved courses must provide written notice to the Department of the dates and location a course will be held. Medication administration training programs are subject to periodic on-site review by the Department.
 - (f) The program coordinator shall be responsible for the completion, signing, and submission to the Department of all required documentation. A coordinator shall be responsible for ensuring that the following requirements are met:
 - 1. course objectives are accomplished;
 - 2. only persons having appropriate skills and knowledge are selected to conduct any part of the training;
 - 3. each trainee demonstrates competence in medication administration through passing a written test and a practical demonstration of skills;
 - 4. records are kept to verify the participation and performance of each trainee in each phase of the training program, the satisfactory completion of the training program by each trainee to be attested on each trainee's record, and
 - 5. issue each trainee a letter of completion. Successful completion shall be documented by a letter provided to the employee and to the provider agency where the person is employed, and signed by the program coordinator for the course. Such letter must contain:
 - (i) the name and current address of the employee;
 - (ii) title of the course;
 - (iii) the employee's date of birth and social security number;

(Rule 1200-20-12-.02, continued)

- (iv) the name(s) of the course instructor(s) and educational sponsor for the course;
 - (v) the provider agency with whom the person is employed or to be employed;
 - (vi) the date of successful completion of the course; and
 - (vii) provide a copy of the letter to the Department.
- (6) Reporting of Competency Testing
 - (a) Any testing entity that administers competency testings shall maintain a list of those who have successfully completed a competency test and shall forward a copy of such list to the provider and/or the approved training program within thirty (30) days of administration of such tests. Such testing entity shall provide additional information as required by the Department by contract with the testing entity.
- (7) Denial, Suspension or Revocation of Approval to Provide Training in Medication Administration
 - (a) The Department shall deny, suspend, or revoke its approval of a Medication Administration Training Program for failure by the training entity to meet the requirements of this rule 1200-20-12-.02 (i.e., Approval of Training Program.) Any denial, suspension, or revocation may be appealed in writing to the Commissioner of the Department of Health. Subsequent appeals shall be made pursuant to the Rules of the Department of Finance and Administration for the purchase of services and the applicable statutes.
- (8) When required by a court order or settlement, documents and information relevant to such order or settlement may be reviewed by other appropriate individuals related to the litigation.

Authority: T.C.A. §§4-5-202 and 68-1-904. **Administrative History:** Original rule filed August 21, 1998; effective November 4, 1998.

1200-20-12-.03 UNLICENSED PERSONNEL

- (1) Any provider agency employee who is not otherwise authorized by law to administer medications in a mental retardation program shall be allowed to perform such duties only after passing a competency test. An employee who administers medications in a program in compliance with the provision of this paragraph shall be exempt from the licensing requirements of the Nurse Practice Act and the Rules of the Board of Nursing.
- (2) Before administering medications, an unlicensed employee must satisfactorily complete a medication administration training program which shall consist of not less than 20 hours of classroom instruction as set forth in 1200-20-12-.02(2).
- (3) To successfully complete a medication administration training program, an unlicensed employee must achieve a score of at least 80% for the course based on a written, objective test on the components set forth in these regulations. Demonstrated proficiency in the practicum of medication administration is also required and shall be determined by the program coordinator administering the course.

(Rule 1200-20-12-.04, continued)

- (4) An employee will be eligible to take the competency test two times. If such individual fails to meet minimum competency requirements in such second test, the employee cannot take the test again, nor shall the employee be allowed to administer medications.

Authority: T.C.A. §§4-5-202 and 68-1-904. **Administrative History:** Original rule filed August 21, 1998; effective November 4, 1998.

1200-20-12-.04 APPROVALS OF UNLICENSED PERSONNEL

- (1) When a new unlicensed employee with prior medication administration training requests to administer medications in a program licensed by or under contract with the Division of Mental Retardation Services, the provider agency shall obtain confirmation from the Department of an employee's approval status, including the date the employee was approved, before the new employee can administer medication.
- (2) The Department shall verify an employee's date of last successful completion of medication administration training program.
- (3) When requested, a provider agency shall notify the Department in writing whenever an approved unlicensed employee has his or her approval to administer medication withdrawn by a provider agency.
- (4) An unlicensed employee shall not be approved if such employee:
 - (a) is less than eighteen years of age;
 - (b) has been convicted of a crime rationally related to his or her employment;
 - (c) has not successfully completed an approved medication administration course;
 - (d) received a grade below 80% for an approved medication administration course;
 - (e) has not been approved by the provider agency to administer medications;
 - (f) has failed to be re-tested every two years on medication administration in accordance with these rules;
 - (g) has failed to retake the medication administration test when such individual has been previously approved to administer medications but has not worked with people with mental retardation/developmental disabilities for a period of six months; or
 - (h) commits medication administration errors which demonstrate lack of competence.

Authority: T.C.A. §§4-5-202 and 68-4-904. **Administrative History:** Original rule filed August 21, 1998; effective November 4, 1998.

1200-20-12-.05 LIMITATIONS ON FUNCTIONS OF UNLICENSED PERSONNEL

- (1) The following procedures may not be performed by unlicensed personnel under the scope of these regulations:
 - (a) endotracheal suctioning;

(Rule 1200-20-12-.05, continued)

- (b) urinary catheter insertion;
 - (c) nasogastric tube care;
 - (d) intravenous therapy;
 - (e) adjustment of doses of medications;
 - (f) tracheotomy care;
 - (g) administration of oxygen;
 - (h) administration of fluxuating or mixing insulin dosages; and
 - (i) administration of medications by subcutaneous, intramuscular, intradermal or intravenous route, except for routine insulin and one time life saving injections, such as Epipens.
- (2) This regulation does not preclude the performance of procedures by unlicensed personnel pursuant to individual delegation by licensed personnel in accordance with the Nurse Practice Act and the Rules of the Board of Nursing.

Authority: T CA. §§4-5-202 and 68-1-904. **Administrative History:** Original rule filed August 21, 1998; effective November 4, 1998.

1200-20-12-.06 PROVIDER AGENCY REQUIREMENTS

- (1) A provider agency or program employing unlicensed personnel must have a written policy and procedure demonstrating compliance with these rules for any employees who administer medications. These policies and procedures must be approved by the Department prior to the implementation of medication administration by unlicensed employees in that provider agency or program.
- (2) A provider agency must have a separate medication administration record (MAR) of medications for each person receiving medication. The record documenting administration must include at least the following:
- (a) name of person receiving the medication;
 - (b) name of medication, dosage and route of administration;
 - (c) time and date of administration;
 - (d) name of prescribing, ordering, or approving practitioner;
 - (e) start and stop dates;
 - (f) expected therapeutic effects for the person taking the medication;
 - (g) possible side effects to the person taking the medication;
 - (h) storage of medications; and

- (i) disposal of medications
- (3) As a condition to authorizing or renewing the authorization to operate any provider agency or program that administers medications to persons with mental retardation/developmental disabilities, the Division shall require that the agency have employees qualified pursuant to these rules on duty at any time that the agency administers such medications. The agency must maintain a written record of each medication administered to each person. Such record will be subject to review by the Division as a part of its procedure in authorizing the continued operation of the provider agency and the provider agency's programs.

Authority: T.C.A. §§4-5-202 and 68-1-904. **Administrative History:** Original rule filed August 21, 1998; effective November 4, 1998.

1200-20-12-.07 SUSPENSION OF AUTHORITY TO ADMINISTER MEDICATION

- (1) In the event the unlicensed employee is determined by the provider agency or program or the Department to be unable to safely administer medications due to the inability to function with reasonable skill and safety for any reason, including, but not limited to, the use of drugs, alcohol or controlled substances which could impair judgment; performance of unsafe or unacceptable care of people receiving services in the administration of medications; or failure to conform to the essential standards and prevailing standards of medication administration, the agency or program shall immediately suspend the authority of the unlicensed employee to administer medication.
- (2) Any such denial or suspension of the unlicensed employee's authority shall be reported to the Department in writing.

Authority: T.C.A. §§4-5-202 and 68-1-904. **Administrative History:** Original rule filed August 21, 1998; effective November 4, 1998.

1200-20-12-.08 MONITORING

- (1) The Department will monitor the administration of medications by unlicensed employees through quality enhancement surveys and follow-up monitoring by registered nurses employed by or contracted with the Department.
- (2) Regarding medication administration, monitoring shall include, but not be limited to, review of each provider agency's evaluation and performance records for unlicensed employees who perform the functions and activities provided for in these rules. Such records shall encompass statements and observations by supervisors of unlicensed personnel made during the course of the work performed by the unlicensed employees. Monitoring may include direct observation of medication administration by unlicensed employees approved pursuant to these rules.

Authority: T.C.A. §§4-5-202 and 68-1-904. **Administrative History:** Original rule filed August 21, 1998; effective November 4, 1998.